No. 89-243

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,
v.
MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF IN SUPPORT OF PETITION ON BEHALF OF PFIZER HOSPITAL PRODUCTS GROUP, INC. AND PFIZER INC. AS *AMICI CURIAE*

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Pfizer Hospital Products Group, Inc. and Pfizer Inc. (collectively "Pfizer") respectfully move this Court, pursuant to Rules 36.1 and 42 of the Rules of the Supreme Court, for leave to file the attached brief as *amici curiae* in the above-captioned case. Pfizer's brief is in support of the Petitioner, and urges that this Court review and reverse the decision below.

Counsel for Petitioner, Eli Lilly and Company ("Lilly"), have consented in writing to the filing of an *amici* brief by Pfizer. No unqualified consent of the Respondent,

Medtronic, Inc., could be obtained, thereby necessitating this motion.

Pfizer Hospital Products Group, Inc. is a research-based manufacturer of medical devices and Pfizer Inc. is its parent organization. Pfizer has been engaged for years in research, development and sale of medical devices and drugs designed to alleviate and cure various conditions destructive of the health of mankind.

The subject Petition of Lilly addresses a decision by the Court of Appeals for the Federal Circuit which held that the infringement exemption set forth in 35 U.S.C. § 271(e)(1) applies to medical devices as well as to drugs and veterinary biological products. Unlicensed use and sale of medical devices were thereby authorized. Pfizer believes that the decision was erroneous and based upon a mistaken perception of the nature of the holding in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), and what the Congress was seeking to accomplish in reversing that holding.

Pfizer possesses a unique historical perspective as an innovator and marketer of both medical devices and drugs. Pfizer believes that this perspective and its experience in day-to-day dealings with the applicable Federal Laws governing sale of these products will assist the Court in better understanding the competing policies and statutory compromises intended by Congress when it enacted the Drug Price Competition and Patent Term Restoration Act of 1984, which the Federal Circuit erroneously interpreted below.

As shown in the attached Brief, the issue decided by the Federal Circuit affects far more than the individual interests of the named parties. The decision below, which holds that the statutory words "drugs or veterinary biological products" include medical devices, adversely impacts on innovation in the medical device industry to the direct detriment of the public interest. Patents directed to a wide variety of lifesaving and quality of life-enhancing devices are now relegated to a second-class and partially unenforceable status.

Given the Constitution, it is questionable whether Congress could have by law restricted a patent owner's rights as occurred below. Most certainly, however, the rights possessed by owners of medical device patents cannot be taken away under the guise of statutory interpretation in the face of clear, contrary statutory language and congressional intent.

Pfizer respectfully requests that the Court permit it to file the attached brief and that Petitioner's request to issue a writ of certiorari to review the judgment and opinion of the Federal Circuit be granted.

Respectfully submitted,

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BRIEF FOR PFIZER HOSPITAL PRODUCTS GROUP, INC. AND PFIZER INC. AS *AMICI CURIAE*

INTEREST OF *AMICI*

Pfizer Hospital Products Group, Inc. and Pfizer Inc. (collectively "Pfizer") are research-based manufacturers of medical devices and drugs. For many years, Pfizer has conducted research and development into such products for which it has received hundreds of United States Patents.

As an innovator and seller of new medical devices and drugs, Pfizer is thoroughly familiar with both the enormous costs required to develop such products and the expensive approval and marketing requirements of Federal Law. Pfizer has participated in the regulatory ap-

proval process since well before Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("1984 Act") which is at issue here.

As a substantial patent owner, Pfizer recognizes the incentives offered by the United States patent system in return for research expenditures and innovation into the cure and alleviation of conditions destructive to the health and well being of man. The decision below affects far more than the named parties. By deciding that the statutory words "drugs or veterinary biological products" include medical devices, the Federal Circuit has rendered patents to such devices partially unenforceable. Patents directed to a wide variety of lifesaving and quality of life-enhancing devices can now be practiced without the owner's consent, thereby reducing the reward and hence the incentive to undertake the enormous expense to develop and market new products.

Pfizer believes that the full scope of patents to medical devices should be restored by this Court. Given the Federal Circuit's exclusive jurisdiction (28 U.S.C. § 1295), no other judicial forum is available to achieve this objective.

ARGUMENT

The Petition should be granted here because the decision below significantly impedes the availability of new medical devices, and it is based on a misreading of congressional intent as well as the decision, *Roche Products, Inc.* v. *Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984) (*"Roche"*), which Congress overruled when it enacted 35 U.S.C. § 271(e)(1). The 1984 Act simply does not say what the Federal circuit claims it does, and the intent of the Congress belies the court's legally erroneous interpretation.

I. THE HOLDING IN *ROCHE* v. *BOLAR*, WHICH CONGRESS REVERSED BY ENACTING 35 U.S.C. § 271(e)(1), WAS LIMITED TO PATENTED DRUG INVENTIONS

A significant portion of the Federal Circuit's decision was devoted to an effort to identify the precise holding in *Roche*. This was because the court quite correctly accepted the following as an explicit statement of congressional intent:

> "The provisions of section 202 of the bill [i.e., the amendment of Title 35 adding section 271(e)(1)] have the net effect of reversing the holding of the court in *Roche*." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2 at 27, *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2711 (Pet. App. 6a)[1]

The Federal Circuit also properly stated that:

> ". . . what is clear to this court, as well as to the parties and the district court, is that section 271(e)(1) was added to overrule this court's decision in *Roche*." (Pet. App. 5a)

In section IV of its opinion (Pet. App. 5a-6a), the court below announced its interpretation of the *Roche* holding. In so doing, not one single word from the *Roche* decision was quoted. The court completely ignored the following clear and certain statement of the holding in *Roche*:

> The district court correctly recognized that the issue in this case is narrow: does the limited use of a patented *drug* for testing and investigation strictly related to FDA *drug* approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable? The district court held that it does not. This was an error of law. *Roche*, 733 F.2d at 861 (emphasis added)

[1] "Pet. App." refers to the Appendix filed by Petitioner, Eli Lilly and Company.

As the legislative history makes readily apparent, this is the precise *holding* (as distinguished from *underlying rationale* and *dicta*) which Congress overruled when enacting 35 U.S.C. § 271(e)(1).

Nothing in *Roche* supports the Federal Circuit's conclusion that the *Roche holding* extended to *all* patented inventions related to products subject to regulatory approval under the Federal Food, Drug and Cosmetic Act (i.e., drugs, medical devices, food additives, color additives, etc.). By enacting 35 U.S.C. § 271(e)(1), Congress did not intend, as the court below implied, to overrule over one hundred fifty years of federal court jurisprudence dating back to *Whittemore* v. *Cutter*, 29 F.Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) on the experimental use defense to liability for infringement. Only a complete misreading of the holding in *Roche* and congressional intent could have led the court to arrive at such an erroneous conclusion.

II. CONTRARY TO THE FEDERAL CIRCUIT'S ASSERTION, PERSUASIVE REASONS DID EXIST FOR CONGRESS' FAILURE TO EXTEND 35 U.S.C. § 271(e)(1) TO MEDICAL DEVICES

The lower court's decision was heavily influenced by the fact that the 1984 Act, which included the new 35 U.S.C. § 271(e)(1), also provided for patent term restoration for drugs, medical devices, food additives and color additives. Following a discussion of statutory construction, the court came to the erroneous conclusion that the only way to make sense out of the 1984 Act was to assume that Congress intended 35 U.S.C. § 271(e)(1) to apply to medical devices, and presumably also food additives and color additives, as well as to drugs (Pet. App. 7a).

In reaching this conclusion, the court cited no legislative history whatsoever and it failed to recognize that the 1984 Act was based upon a desire to promote two significant congressional policies. Neither of these policies *per se* involved overruling *Roche*. First, the 1984 Act contained provisions for patent term restoration for drugs, medical devices, food additives and color additives. Second, the 1984 Act included abbreviated testing procedures for regulatory approval of generic substitutes for patented drugs so that generic drug substitutes could be marketed promptly after expiration of patents covering the drug. These provisions for expedited marketing of generic substitutes applied to drug products *only*. There were no comparable provisions for abbreviated testing for "generic" medical devices.[2] Under the *Roche* holding, the abbreviated testing procedures for generic drug substitutes constituted patent infringement, and so Congress had to make a very limited exception to the law of infringement to carry forward its second policy objective.

Without question, Congress intended 35 U.S.C. § 271(e)(1) to apply to drugs only because Congress, in enacting the 1984 Act, reasoned as follows: (1) patent term restoration for drugs, medical devices, food additives and color additives was, in and of itself, desirable; (2) abbreviated testing procedures for generic substitutes of patented drugs to permit the marketing of such generic drug substitutes promptly after patent expiration was also desirable; and (3) in order to realize objective (2), 35 U.S.C. § 271 had to be amended (as in 35 U.S.C. § 271(e)(1)) for patented *drug* inventions only.

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[2] The legislative history of the 1984 Act shows no significant input by the manufacturers of "generic" medical devices.

CONCLUSION

The decision of the Federal Circuit below, in an area where it has no special expertise, is a clear error of law. It will have an adverse impact on companies which innovate, develop, and market medical devices, and consequently on those who would use and benefit from such devices. The impact extends far beyond the parties to this case. Patent owners in this field now hold patents which cannot be enforced against unlicensed use, even though the unlicensed users reap significant benefits, both economically and business-wise.

This disincentive to innovation arises from a plain error in statutory construction. This clear error of law should be corrected by this Court.

Respectfully submitted,

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